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|--|---------------|----------------------|-----------------------|------------------|
| APPLICATION NO.  | FILING DATE   | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.   | CONFIRMATION NO. |
| 10/597,977   | 09/12/2006    | Michael Harold Rock  | 05432/1200962-US1     | 8787             |
| 7278   | 7590          | 07/01/2010           | EXAMINER              |                  |
| DARBY & DARBY P.C.<br>P.O. BOX 770<br>Church Street Station<br>New York, NY 10008-0770 |               |                      | COLEMAN, BRENDA LIBBY |                  |
| ART UNIT   | PAPER NUMBER  |                      | 1624                  |                  |
| MAIL DATE  | DELIVERY MODE |                      |                       |                  |
| 07/01/2010   | PAPER         |                      |                       |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                    |
|------------------------------|--------------------------------------|------------------------------------|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/597,977 | <b>Applicant(s)</b><br>ROCK ET AL. |
|                              | <b>Examiner</b><br>Brenda L. Coleman | <b>Art Unit</b><br>1624            |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 31 March 2010.  
 2a) This action is FINAL.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1,3-47,53 and 54 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) 35-37 is/are allowed.  
 6) Claim(s) 1,6,19-34,38-47,53 and 54 is/are rejected.  
 7) Claim(s) 3-5 and 7-18 is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_  
 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

**DETAILED ACTION**

Claims 1, 3-47, 53 and 54 are pending in the application.

This action is in response to applicant's amendments dated March 31, 2010.

Claims 1, 3-19 and 53 have been amended and claims 2, 48 and 52 have been canceled.

***Response to Arguments***

Applicant's arguments filed March 31, 2010 have been fully considered with the following elect:

1. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, first paragraph rejection labeled paragraph 2) in the last office action, which is hereby **withdrawn**.
2. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections labeled paragraph 3a) and b) in the last office action, which are hereby **withdrawn**. However, with regards to the 35 U.S.C. § 112, second paragraph rejections labeled paragraph 3c), d), e), f) and g) in the last office action, the applicant's amendments and remarks have been fully considered but they are not persuasive.

c-g) The applicants' stated that Claims 3, 7, 10, 14 and 17 are directed generally to a crystalline form of compound I whereas claims 22, 25, 28, 31 and 34 are directed to "[s]olid compound I containing a crystalline Compound I" form. However, the crystalline form of compound I of claims 3, 7, 10, 14 and 17 fail to

differ from the solid of claims 22, 25, 28, 31 and 34 since a compound is not crystalline unless it is a solid and thus the claims are substantial duplicates of the corresponding claims.

Claim 22 is a duplicate of claim 3, for reasons of record and stated above.

Claim 25 is a duplicate of claim 7, for reasons of record and stated above.

Claim 28 is a duplicate of claim 10, for reasons of record and stated above.

Claim 31 is a duplicate of claim 14, for reasons of record and stated above.

Claim 34 is a duplicate of claim 17, for reasons of record and stated above.

3. With regards to the 35 U.S.C. § 102(b) anticipation rejections of claims 1-48 and 52-54 labeled paragraph 4, in the last office action, the applicant's arguments have been fully considered but are not found persuasive. The applicants' stated that there is no basis for asserting Kaneko discloses Compound I in crystalline form. While it is acknowledged that claims 3-18, 22, 25, 28, 31, 34-37, 41 and 42 are to specific polymorphic forms such that their polymorphic characteristics are included in the claim. However, Kaneko teaches the compound 8 which indicates the IR and NMR of the final product which is a solid form. Claims 1, 19-21, 23, 24, 26, 27, 29, 30, 32, 33, 38-40, 43-47, 53 and 54 are to crystalline, solid or compositions of Compound I without any indication that they possess specific crystalline properties. Kaneko teaches the solid compound 8 which per applicant's own specification is used in their own process.

Polymorphs are distinguishable by various analytical techniques, especially X-ray powder diffraction patterns. With regards to the compositions the Carnegie Mellon Department of Physics teaches that the common industry practice when formulating a

new drug to manufacture in dosage form is to rely on formulations (composition of inert additives) that worked with other drugs in the past. When this procedure fails (as is often the case) the formulation is changed by trial-and-error. The challenge is exacerbated by the fact that the formulation must achieve numerous, possibly competing objectives, such as control of chemical stability, disintegration and dissolution rates, polymorphism, crystal habit, and dosage uniformity. Because these systems have such complex compositions, and interactions between two or more formulation components often lead to unexpected consequences for one or more of the design objectives; there are few reliable, rational formulation design rules. Some formulations preserve the correct polymorph, others do not, and the reasons are usually not understood. This is a severe barrier in the pharmaceutical industry. Our aim is to develop new tools to give fundamental insight into identifying and controlling polymorphism in industrial processes through a molecular-level understanding. The applicants are not specifically claiming solid pharmaceutical compositions, but a composition comprising Compound I.

Claims 1, 19-21, 23, 24, 26, 27, 29, 30, 32, 33, 43-47, 53 and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaneko, Journal of Medicinal Chemistry, for reasons of record and stated above.

In view of the amendment dated March 31, 2010, the following new grounds of rejection and/or reinstated rejections apply:

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 6, 39-44 and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reason(s) apply:

- a. Claim 6 is vague and indefinite in that it is not known what is meant by the amendment to the claim where P2;2,121 has been amended to P212121.
- b. Claim 39 and claims dependent thereon are vague and indefinite in that it is not known what is meant by the period which appears at the end of the third line indicating the end of the claim which is not so.
- c. Claim 44 and claims dependent thereon are vague and indefinite in that it is not known what is meant by the period which appears at the end of the third line indicating the end of the claim which is not so.

***Claim Objections***

5. Claims 3-5 and 7-18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Allowable Subject Matter***

6. Claims 35-37 are allowed. None of the prior art or record or a search in the pertinent art area teaches the process of preparing crystalline Compound I as claimed herein.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status

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information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brenda L. Coleman/  
Primary Examiner, Art Unit 1624